IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Namenda Direct Purchaser Antitrust Litigation **THIS DOCUMENT RELATES TO:** **All Direct Purchaser Actions**	**Case No. 1:15-cv-07488-CM (JF)**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISQUALIFY DR. LON SCHNEIDER

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Defendants[1] bring this motion to disqualify Dr. Lon Schneider, a consultant to Defendants on Namenda, the drug at issue in this case. Dr. Schneider was formally retained by Defendants in connection with (1) studies on the efficacy of memantine upon which the FDA's approval of Namenda IR was based and (2) the Namenda IR New Drug Application ("NDA") which resulted in the listing of the `703 patent upon which the Hatch-Waxman patent litigations at issue in this case are premised. It also appears that Dr. Schneider was retained by Forest as an expert in the Namenda IR Hatch-Waxman patent litigations now at issue in this action. Dr. Schneider's work for Defendants implicates topics directly at issue in this case and threatens disclosure of Defendants' confidential information, including mental impressions, litigation strategy, and product development. He has had an extensive entanglement with Forest and with the drug at issue in this case, going so far as to identify himself as a consultant for Forest when being quoted in the media and serving as a Namenda Advisory Board member. In those roles he has had or would be expected to have had access to Forest's confidential information, and in any event cannot realistically be expected to be able to disassociate what he knows by virtue of that access to confidential information from information he may have gained independently. It is unfair for Forest to bear the risk that its confidential information be used against it in litigation by its former consultant, particularly where there is no shortage of neurologists who have Alzheimer's Disease expertise who are not so conflicted. To allow Dr. Schneider to act against Forest in this action at the very least creates an appearance of impropriety. Accordingly, the

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[1] "Forest" refers to Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Forest Laboratories, LLC, collectively with Actavis, plc, "Defendants."

Court should disqualify Dr. Schneider as an expert for Plaintiffs,[2] preclude Plaintiffs' consultation with Dr. Schneider, and prohibit Plaintiffs from disclosing Forest's confidential information to Dr. Schneider.

I. DR. SCHNEIDER'S EXTENSIVE HISTORY WITH FOREST

Dr. Schneider's involvement with Forest and Namenda dates back at least fourteen years. He has consulted for Forest in various capacities since at least 2003 on a variety of issues directly related to Forest's research, development, and approval of Namenda and Alzheimer's treatments.

Months prior to the FDA's approval of Namenda IR, Dr. Schneider entered into a Consultant Agreement with Forest Research Institute, a division of Forest Laboratories, Inc., for [redacted] Consultant Agreement between Forest Laboratories, Inc. and Dr. Lon Schneider dated May 2, 2003; McDevitt Ex. A ("NDA Retainer"). The NDA Retainer contained an explicit confidentiality provision in which Dr. Schneider agreed to [redacted] McDevitt Ex. A at 2.

Dr. Schneider's obligations under the NDA Retainer lasted for [redacted] beyond the termination. McDevitt Ex. A at 2. While the precise termination date is unknown, at a minimum, the confidentiality provisions in the NDA Retainer lasted through the commencement, litigation, and settlement of many of the Namenda IR patent litigations at issue in this case.

Dr. Schneider presented in September 2003, a month before the FDA approved Forest's NDA on Namenda IR, at an FDA Advisory Meeting on memantine efficacy in Alzheimer's

[2] Direct Purchaser Plaintiffs, also referred to as "DPPs."

Patients. *See* "Memantine Efficacy in Moderate to Severe AD," Lon Schneider, M.D. (Sept. 2003), McDevitt Ex. B.

Also in 2003, Dr. Schneider entered into a second retention agreement with Forest, this time as a consultant on two memantine studies, MEM-MD-01 and MEM-MD-12. Consultant Agreement between Dr. Lon Schneider and Forest Laboratories dated Dec. 4, 2003; McDevitt Ex. C at 1 ("Clinical Study Retainer"). Again, the Clinical Study Retainer contained a confidentiality provision, the terms of which expired seven years following the termination of the engagement. McDevitt Ex. C at 2. As in the NDA Retainer, the Clinical Studies Retainer explicitly states that Dr. Schneider "[redacted] McDevitt Ex. A at 2; McDevitt Ex. C at 2.

In addition to these consulting engagements with Forest, Dr. Schneider's vast array of subsequent medical publications also detail his extended relationship with Forest. Dr. Schneider himself, in his own publications and panel involvements, identifies himself as a "consultant for Forest" in at least 2004, 2005, 2006, 2007, 2008, 2011, 2012, and 2014.[3]

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[3] *See, e.g.*, Peter V. Rabins et at., *Guideline Watch (Oct. 2014): Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias* 1 (2014); Cynthia A. Munro et al., *Cognitive Outcomes after Sertaline Treatment in Patients with Depression of Alzheimer's Disease*, 20(12) AM. J. GERIATRIC PSYCHIATRY 1036 (2012); Lon S. Schneider et al., *Lack of Evidence for the Efficacy of Memantine in Mild Alzheimer Disease*, 68;8 ARCH NEUROL 991, 997 (2011); *Clinical Antipsychotic Trials of Intervention Effectiveness* (CATIE) study, DEMENTIAGUIDE (May 12, 2008), https://www.dementiaguide.com/community/dementia-articles/?pageContent=clinical-antipsychotic (citing Lon S. Schneider et al., *Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer's Disease,* 355;15 NEW ENG. J. MED. 1525, 1537 (2006)); Peter V. Rabins et at., *Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias* 2 (Laura J. Fochtmann ed., 2d ed. 2007); Lon S. Schneider et al., *Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer's Disease*, 355;15 NEW ENG. J. MED. 1525, 1537 (2006); Rupert McShane &

Given Dr. Schneider's involvement in the clinical studies and NDA approval of Namenda IR, it is unsurprising that when Hatch-Waxman patent litigation (now at issue in this action) arose following the filing of generic Namenda IR ANDAs, Forest's patent counsel at the time, Kirkland & Ellis, approached Dr. Schneider for expert support of Forest's claims of infringement against generic Namenda IR ANDA filers. There is evidence, which Forest is prepared to provide for *in camera* review, because it is privileged, that Dr. Schneider consulted with Forest's counsel, Kirkland & Ellis, regarding the Namenda IR patent litigations and agreed to serve as an expert for Forest in those litigations. That agreement was memorialized in a June 2008 letter sent from Forest to Dr. Schneider stating that Forest and Merz "[redacted] Letter from E. Agovino to Dr. Schneider dated June 2 2008; McDevitt Ex. F at 1 ("Patent Litigation Retainer"). Like the two previously identified consulting agreements, the Patent Litigation Retainer included a confidentiality provision but this one continues indefinitely: [redacted] McDevitt Ex. F at 2.[4]

In 2009, Dr. Schneider served as an "Executive Advisor" on memantine for Forest. McDevitt Ex. G; McDevitt Ex. H. Executive Advisors to Forest obtained feedback and input

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Lon S. Schneider, *Meta-analysis of Memantine: Summary and Commentary*, 1 J. ALZHEIMER'S ASS'N 67 (July 2005); *Memantine: Implications for Treating Alzheimer's*, ALZFORUM (Sept. 29, 2004), http://www.alzforum.org/webinars/memantine-implications-treating-alzheimers.

[4] Forest does not have access to further factual background regarding the interactions between Forest's counsel at Kirkland & Ellis, Gerald Flattmann and Melanie Rupert, and Dr. Schneider. Mr. Flattmann and Ms. Rupert have since transitioned to another firm and no longer have access to files or emails which could flush out the details of Dr. Schneider's ultimate retention for those litigations.

from Forest on issues relevant to product launches. McDevitt Ex. I. In Dr. Schneider's case, his role on the Executive Advisory Board was coincident with the "impending launch of Namenda XR," which DPPs assert was part of an anti-competitive scheme undertaken by Forest. McDevitt Ex. I; *see, e.g.*, Am. Compl. ¶¶ 13, 143-192. Dr. Schneider was thus requested by Forest to provide feedback on the marketplace for Forest's Alzheimer drugs and "[redacted]." McDevitt Ex. I. In the years following Namenda XR's approval, Dr. Schneider continued to "serve[] as a consultant or on advisory panels."[56]

On May 23, 2017, Plaintiffs in this action disclosed Dr. Lon Schneider as an expert for Plaintiffs. McDevitt Decl. ¶ 27. Pursuant to the Stipulated Amended Protective Order, Defendants objected in writing to Plaintiffs' retention of Dr. Schneider on May 31, 2017. McDevitt Decl. ¶ 28. The parties met and conferred regarding Defendants' objections two days later. Defendants expressed preliminary concerns stemming from Dr. Schneider's potential

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[5] "Guideline Watch (October 2014): Practice Guideline For The Treatment Of Patients With Alzheimer's Disease And Other Dementias," Lon Schneider, M.D., et al. (Oct. 2014), available at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/ guidelines/ alzheimerwatch.pdf.; Study: Popular Alzheimer's drug ineffective for mild cases, CNN, Apr. 12, 2011, available at http://www.cnn.com/2011/HEALTH/04/11/alzheimer.drug. ineffective/index.html; "Cognitive Outcomes after Sertaline Treatment in Patients with Depression of Alzheimer's Disease," Lon Schneider, M.D., et al. (Dec. 2012).

[6] Additionally, in December 2014, Forest believes that Dr. Schneider agreed to join an amicus brief in support of Forest's expedited appeal to the Second Circuit of Judge Sweet's preliminary injunction preventing Forest's withdrawal of Namenda IR based on the "product hop" allegations (a claim also asserted by DPPs in this action). Forest understands that Dr. Schneider engaged with Mr. Bradford Glassman of Lewis Baach PLLC regarding joining an amicus brief, including reviewing attorney work-product, a near-final version of the brief sent to him on January 14, 2015, after which time Dr. Schneider ultimately decided not to join the brief. Unfortunately, details of those conversations, and the extent to which confidential Forest information, including business plans and litigation strategy, was revealed in those conversations are unknown as Mr. Glassman, who authored the Brief of Physician Amici Curiae in Support of Defendants-Appellants in State of New York v. Actavis plc, Dkt. No. 208, 14-cv-4624 (2d Cir. Jan. 22, 2015), passed away in July 2015.

involvement with (1) the Namenda NDA; (2) other Allergan drugs; (3) the Physician's Amicus Brief in the NYAG Action; and (4) the Namenda IR patent litigation. McDevitt Decl. ¶ 29. Plaintiffs expressed their belief that "none of the information … disclosed thus far convinces us that Dr. Schneider is disqualified in this case." *Id.* Plaintiffs maintained that any confidential disclosures to Dr. Schneider in connection with the NDA filing out-of-hand would not be relevant in this litigation and that Defendants had not presented enough facts to merit disqualification. Despite good faith efforts to negotiate, the parties reached an impasse on June 13, 2017. McDevitt Decl. ¶ 31.

II. ARGUMENT

This Court "has the inherent power to disqualify an expert witness when such relief is warranted," such as where a conflict of interest arises. *Rodriguez v. Pataki*, 293 F. Supp. 2d 305, 311 (S.D.N.Y. 2003); *see also Grioli v. Delta Int'l Mach. Corp.*, 395 F. Supp. 2d 11, 14 (E.D.N.Y. 2005) (aggregating Southern District of New York cases). While there is no "bright line rule" set by the Second Circuit, district courts within this Circuit typically consider three elements in determining whether an expert should be disqualified: (1) the existence or reasonable expectation of a confidential relationship between the movant and the expert; (2) whether the movant in fact disclosed confidential information to the expert; and (3) the public's interest in preserving judicial integrity and fairness balanced against the party's right to the assistance of experts who possess specialized knowledge. *Auto-Kaps, LLC v. Clorox Co.*, 2016 U.S. Dist. LEXIS 37097, at *7 (E.D.N.Y. Mar. 22, 2016). Disqualification of an expert serves to "prevent the risk of prejudice from possible disclosure and the fundamental unfairness that would arise." *Id.* at *9.

Forest recognizes that parties moving to disqualify an expert typically present a detailed showing, often through declarations and exhibits, evidencing the entanglement between the proposed expert, the confidential information received, and the litigation at hand. As noted, due to both the passage of time and numerous changes in corporate form at Forest that post-date the beginning of Dr. Schneider's involvement with memantine nearly fifteen years ago, Forest cannot make as detailed of a showing in support of this motion for disqualification. Since Dr. Schneider began consulting for Forest on memantine, Forest has undergone multiple acquisitions, each accompanied by significant turnover in personnel.[7] The individuals who initially worked with Dr. Schneider are no longer with the company, and Forest's access to the details concerning their exchanges with Dr. Schneider therefore is not available. Nevertheless, the critical facts are uncontestable: Dr. Schneider had a direct relationship with the issues relevant in this litigation. Dr. Schneider was associated with every aspect of matters at issue in this litigation, including the original Namenda IR NDA, the Hatch-Waxman patent litigations on Namenda IR, and the New York Attorney General's allegations of the product hop. Disqualification of Dr. Schneider is warranted on this basis alone.

[7] Forest Labs was acquired by Actavis plc in July 2014. Allergan, Inc. acquired Actavis plc acquired Allergan, Inc. in March 2016, and thereafter assumed the "Allergan" name. See Press Release, "Actavis Completes Forest Laboratories Acquisition," July 1, 2014, available at https://www.allergan.com/NEWS/News/Thomson-Reuters/Actavis-Completes-Forest-Laboratories-Acquisition; Press Release, "Actavis Completes Allergan Acquisition," March 17, 2015., available at https://www.allergan.com/news/news/thomson-reuters/actavis-completes-allergan-acquisition; Press Release, "Actavis plc is now Allergan plc," June 15, 2015., available at https://www.allergan.com/news/news/thomson-reuters/actavis-plc-is-now-allergan-plc.

1. The Signed Consultant Agreements Evidence a Reasonable Expectation of Confidentiality

Forest enjoyed a reasonable expectation of confidentiality with Dr. Schneider. Courts "must only look to [Forest's] belief of the existence of a confidential relationship, and not the effects of that belief." *AstraZeneca Pharm., LP v. Teva Pharm., USA, Inc.*, 2007 U.S. Dist. LEXIS 88996, at *7 (D.N.J. Dec. 4, 2007). The standard is "not a high hurdle to clear." *Id.* at *5. A reasonable expectation of confidentiality is satisfied where the proposed expert has been subject to express, written confidentiality agreements regarding the relevant drug. *See id.* (finding a reasonable expectation of confidentiality where "[t]he documents, at the very least, evince an intent by the signatories to keep certain types of information regarding questiapine and Seroquel, e.g. clinical, business, and marketing, confidential"). Here, the existence of at least two executed Consultant Agreements, each with explicit confidentiality requirements, is sufficient to satisfy the first prong of the analysis. As even a non-executed retainer can evidence a reasonable expectation of confidentiality, Dr. Schneider's position on the Advisory Committee and oral agreement (even if the retention letter may not have been formally executed) to consult on the IR patent litigations only further support Forest's reasonable expectation of privacy. *See Stencel v. Fairchild Corp.*, 174 F. Supp. 2d 1080, 1084 (C.D. Cal. 2000) ("[T]he exchange of the Retainer Agreement, though not finalized, is persuasive evidence that [counsel] could reasonably rely on [a prospective expert] to preserve the confidentiality of any statements made, since the Agreement itself indicates that understanding between the parties.")

2. The Various Entanglements Dr. Schneider Has Had with Forest and Namenda Over the Past Fifteen Years Strongly Suggest Receipt of Confidential Information

Dr. Schneider's work on the Namenda IR NDA, consulting on the Namenda IR clinical studies, and ongoing role on the Advisory Committee are all positions in which it is highly likely that Dr. Schneider received Forest's confidential information.[8] For instance, the technical details of Namenda IR that Dr. Schneider must have learned from the NDA work are significant for DPPs' allegations concerning the patent litigation settlements. The Namenda IR technical details that Dr. Schneider must have learned from his work with Forest are inextricably related to DPPs' allegations concerning the patent case and resulting settlements. DPPs claim that the settlements improperly extended Forest's Namenda exclusivity beyond what would have occurred had Forest's generic competitors fully litigated their defenses of non-infringement and patent invalidity. Scientific details concerning Namenda—how it was discovered, how it works, what its scientific and clinical attributes are—would have been at the very heart of those defenses, and therefore will presumably be central to DPPs' argument that the settlements were anticompetitive because the defenses were strong. Permitting Dr. Schneider to use technical information gleaned from his work with Forest against Forest in this case—or even permitting the possibility that he might do so, even unwittingly—is fundamentally unfair to Defendants. *See, e.g.*, *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2000 U.S. Dist. LEXIS 321, at *1 (S.D.N.Y. Jan. 20, 2000) (disqualifying "independent consultant" who had worked on the moving party's FDA filings).

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[8] It is also conceivable that confidential information was exchanged during the preliminary discussions regarding retention for the Namenda IR patent litigation or joining the Second Circuit amicus brief.

As just one example, the generic companies in the patent case argued that the scientific data in Forest's '703 patent were insufficient for a scientist to understand how memantine worked to treat Alzheimer's (or whether it worked at all), and therefore the patent was invalid. Dr. Schneider's understanding of similar data (or the very same data) based on Forest's confidential testing and development of memantine—details he would have gleaned only through his prior relationship with Forest—may well bear on these patent invalidity issues. DPPs should not be permitted to use this confidential technical knowledge against Forest, particularly where there is no shortage of other potential experts for them to retain.

In *Auto-Kaps,* the Eastern District of New York held that it was reasonable to infer that a proposed expert had received confidential information when he "consulted on the very project that culminated in the bottle design at issue in this litigation." 2016 U.S. Dist. LEXIS 37097, at *10-11. The court explained:

> It is also not difficult to infer that Foster was given or exposed to confidential information relating to Clorox's strategy regarding its intellectual property. Foster was likely exposed throughout his consultancy to the goals and priorities for the Starblaster project, which Foster may inadvertently use to determine whether the Smart Tube bottle met certain claim limitations of the '743 Patent …

Id. at *12. Strikingly similar to the proposed expert in *Auto-Kaps*, here Dr. Schneider worked in *at least* two capacities on the NDA for Namenda IR—the drug that is at the heart of this litigation.

Similarly, participation on a board for the product at issue evidences the receipt of confidential information, even where the expert himself claimed to have not received any confidential information in connection with serving on the board. *See AstraZeneca*, 2007 U.S. Dist. LEXIS 88996, at *10 (disqualifying expert, despite his assertion that he did not receive confidential information at a conference, as "[t]he doctor's layman comprehension of

'confidential' as a legal term does not carry the heft to sway the Court's reasoning"). Dr. Schneider's multi-year role on the Advisory Committee again strongly suggests receipt of confidential information.

Disclosure of Forest's confidential information would be inevitable throughout the tenure of Dr. Schneider's consultancies with Forest. Not only is it undisputed that Dr. Schneider consulted for Forest on the NDA for Namenda IR, but evidence suggests that Dr. Schneider even presented to the FDA, on behalf of Forest, advocating for the benefits of memantine in mild to severe Alzheimer's patients—the indication for which Namenda XR was later approved. McDevitt Decl. B. At least one of the memantine studies that Dr. Schneider worked on was also produced in the IR patent litigation. McDevitt Decl. D. Dr. Schneider knows, or at least should be held to have known, Forest's strategies surrounding the development of memantine, including Namenda IR. Dr. Schneider knows, or at least should be held to have known, Forest's strategies with respect to the filing of the `703 Patent for memantine. If nothing else, Dr. Schneider has broad knowledge of the Namenda IR patent litigations from whatever communications he had with Forest's counsel that led Kirkland & Ellis to send him a retainer letter. Additionally, Namenda IR was the first in a line of incremental improvements leading up to the fixed-dose combination, Namzaric. There is a strong likelihood, especially given the extensive development and lead time that goes into pharmaceutical development, that throughout his consulting work on the Namenda IR product, Dr. Schneider could also have been apprised of Forest's confidential plans concerning development, marketing, and strategy of its next generation Namenda products, including Namenda XR and Namzaric. Just as in *Auto-Kaps*, it is "not difficult to infer" that Dr. Schneider "was given or exposed to confidential information

relating to [Forest's] strategy regarding its intellectual property" due to his consultancy on the drug at issue in this action.

3. Any Confidential Information Dr. Schneider Obtained from Forest During His Numerous Relations with the Company Cannot Be Meaningfully Separated from His Retention in This Litigation

Particularly where, as here, the proposed expert's prior involvement touches on the issues at the very crux of the present litigation, disqualification is also appropriate due to the inability to differentiate the confidential information obtained previously from the expert's independent knowledge. *Michelson v. Merrill Lynch Pierce Fenner & Smith*, 1989 U.S. Dist. LEXIS 3013, at *9-10 (S.D.N.Y. Mar. 28, 1989) ("a single individual has all the information; try as he might, [the proposed expert] cannot possibly create separate spaces within his memory"); *Auto-Kaps*, 2016 U.S. Dist. LEXIS 37097, at *13-14 ("Foster cannot be expected to catalogue information he received while consulting for Clorox on its design and to then compartmentalize confidential information from the rest of his experience in the dispensing systems industry. This is particularly the case where the design of the Smart Tube's dispensing system is at the very heart of the litigation. Foster will necessarily rely on his decades of experience in the area … in order to determine whether the Clorox Smart Tube bottle infringes the `743 Patent."). With no disrespect, it is irrelevant that Dr. Schneider now states that the confidential information received has no bearing on this litigation (McDevitt Decl., ¶¶ 29, 31). As the *Auto-Kaps* case identified, "the danger is that no one may know how the information he learned … may affect his opinion and Foster may inadvertently use confidential information." 2016 U.S. Dist. LEXIS 37097, at *13. First, this case is in active discovery and any number of technical issues could become relevant as the case progresses. It is too early for any definitive assertions as to what may or may not be relevant. Moreover, even assuming it were possible to definitively pinpoint at this

juncture every technical issue which may bear on the case, an expert who consulted closely with the material directly at issue quite some time ago, as is the case here, cannot reasonably be expected to differentiate between what he learned as a result of that confidential consulting arrangement and what is independently learned knowledge. *See Michelson*, 1989 U.S. Dist. LEXIS 3013, at *10, 14 (acknowledging the "risk" that the proposed expert "will minimally be subconsciously affected by the information he received previously" because "a single individual has all the information" and "cannot possibly create separate spaces within his memory").

4. The Public Association of Dr. Schneider with Both Forest and Namenda Creates an Appearance of Impropriety Further Supporting Disqualification

Numerous times over the past decade, Dr. Schneider has been publicly affiliated with Forest and specifically Namenda. For example, the national media has repeatedly cited Dr. Schneider as a consultant for Forest. For example, a September 24, 2003 article in the Los Angeles Times entitled "FDA Panel Urges Approval of Alzheimer's Medication" said:

> A patient taking Memantine would "stabilize in aspects of thinking, of attention, of participating in daily activities," said Dr. Lon S. Schneider, an advisor to Forest Laboratories and a USC professor of psychiatry, neurology and gerontology.

Mary MacVean, *FDA Panel Urges Approval of Alzheimer's Medication*, Los Angeles Times, Sept. 25, 2003, available at http://articles.latimes.com/2003/sep/25/nation/na-drug25. Dr. Schneider has also disclosed in countless medical publications his consultancy with Forest. *See, e.g.*, Lon Schneider, M.D., et al., *Meta-analysis of memantine: Summary and Commentary on the Cochrane Collaboration's systematic review*, Alzheimer's & Dementia: The Journal of the Alzheimer's Association (July 2005) ("[Lon Schneider] has been a consultant with Forest Laboratories, Inc. and has received an honorarium from Merz Pharmaceuticals, both manufacturers and marketers of memantine."). Further, Dr. Schneider served on the Advisory

Committee for Forest regarding the Namenda product line for at least two years. To allow Dr. Schneider to then opine on the very drug with which he has been so publicly affiliated is not only inappropriate, but presents an appearance of impropriety before the jury and the public at large strongly supporting disqualification. *Michelson*, 1989 U.S. Dist. LEXIS 3013, at *14 (disqualifying expert where "permitting him to testify would at best create an appearance of impropriety and at worst compromise the proceedings by providing plaintiff with confidential information").

5. The Risk to Forest Far Outweighs Any Alleged Burden to Plaintiffs

Given the numerous ways in which Dr. Schneider is connected to issues squarely pertinent to this case, and the public policy considerations behind the Court's inherent power to disqualify experts, the significant risk of prejudice to Forest stemming from Dr. Schneider's incorporation of Forest's confidential information into his analysis far outweighs any prejudice that DPPs may encounter in obtaining a new expert. When Forest entered into its first Consultant Agreement with Dr. Schneider, it had an objectively reasonable expectation of confidentiality given the non-disclosure provisions in the agreement. That expectation of confidentiality was strengthened by each subsequent engagement with Forest, as Dr. Schneider continued to enter into agreements and to broaden his exposure to Forest's confidential information, building from the clinical memantine studies for the NDA to development, marketing, and strategy of the entire Namenda product line through his work in more recent years on the Advisory Committee. Disqualification is appropriate where "there is a risk of disclosing, even inadvertently, confidential information." *Auto-Kaps*, 2016 U.S. Dist. LEXIS 37097, at *5. It would be fundamentally unfair for Forest's reasonable expectation of confidentiality to be eviscerated by the fact that personnel turnover and the passage of time have

rendered unavailable details from those Forest individuals with whom Dr. Schneider worked. And from a public policy standpoint, in light of Forest's preliminary showing of the numerous occasions for which there is strong evidence to suggest Dr. Schneider had access to confidential information directly pertinent to this litigation, it would be fundamentally unfair to put the risk of disclosure on Forest merely because other individuals can no longer lend the narrative details to chronicle Dr. Schneider's communications with the company over the past fifteen years. The presence or absence of those individuals should not be the determining point of the analysis—Dr. Schneider should be.

Neither party contests that Dr. Schneider consulted on the Namenda IR NDA, that the Namenda IR NDA resulted in the listing of the `703 Patent in the Orange Book, and that the generic ANDAs and contentions regarding the `703 Patent were the focal point of the Namenda IR patent litigation. Further, neither party contests that the Namenda IR patent litigation is the basis of Plaintiffs' Section I claims. *See* First Am. Complaint, Dkt. No. 26 (Oct. 13, 2015), ¶¶ 258-274. Above and beyond that, Forest has presented evidence that Dr. Schneider also consulted for Forest on at least two clinical studies on memantine and served on Forest's Advisory Committee for at least two years. Where there is a risk of even inadvertent use of confidential information, Plaintiffs should present "evidence that would outweigh the public's interest in preserving judicial integrity." *Auto-Kaps*, 2016 U.S. Dist. LEXIS 37097, at *15. There is no prejudice to Plaintiffs where other Alzheimer's experts are available. *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 2007 U.S. Dist. LEXIS 92307, at *14-15 (D.N.J. Dec. 17, 2007) (granting motion to disqualify where other technical expert witnesses were available "who may substitute [the proposed expert's] expert opinion"); *see also Domercant v. State Farm Fire & Cas. Co.*, 2013 U.S. Dist. LEXIS 199684, at *10-11 (N.D. Ga. May 15, 2013) (disqualifying

expert where party opposing disqualification "d[id] not, and indeed [could not], show that Cooper is the only such person with such specialized knowledge"). In light of the number of neurologists who specialize in Alzheimer's Disease in the United States, to allow someone who has consulted for Forest on so many aspects of the substance behind Plaintiffs' claims to opine against Forest here would be fundamentally unfair, particularly where it is impossible to discern what Dr. Schneider knows about memantine and Namenda from his work with Forest and what knowledge he independently obtained. *See Michelson*, 1989 U.S. Dist. LEXIS 3013, at *14 ("the prejudice to [the party proposing the expert] is not such that it overcomes the risk that [the expert] will minimally be subconsciously affected by the information he received previously from defense counsel"). Importantly, where Plaintiffs have made every effort in this case to gain access to Forest's confidential, subjective beliefs regarding Namenda and the '703 patent, the Court should exercise extreme caution here in letting Plaintiffs retain, out of all the available neurologists out there, former Forest consultants that may have had access to those very subjective beliefs and confidential assessments while working with Forest on the Namenda NDA.

* * *

Because Forest had a reasonable expectation of a confidential relationship with Dr. Schneider and—consistent with that reasonable expectation—disclosed to him confidential information pertinent to this litigation, the Court should grant this motion.

Dated: June 15, 2017

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